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Indian Government strengthens clinical trials regulations

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Bangalore: In a bid to strengthen the regulation and monitoring of clinical trials in the country, the Indian Government has announced several measures to strengthen the regulation and monitoring of clinical trials in the country. Union Minister for Health and Family Welfare Mr Ghulam Nabi Azad announced these measures in the Lok Sabha recently in response to a question.

12 new drug advisory committees (NDACs) and Six medical device advisory committees (MDACs) have been constituted to evaluate clinical trials proposals. These committees consist of leading experts from central and state government medical institutions. Also a draft notification has been issued for incorporation of a new rule in the Drugs and Cosmetics Rules, 1945, which addresses issues such as medical treatment and financial compensation to the trial subjects in case of trial related injury or death and the procedure for payment of financial compensation. Also an enhancement of responsibilities of ethics committee (EC), sponsor and investigator has been called for ensuring that financial compensation as well as medical care is provided to the trial subjects who suffer trial related injury or deaths and such information is provided to DCGI.

One of the significant measures has been the amendment of the format for obtaining informed consent of trial subjects to include the details of address, occupation, annual income of the subject so as to have information regarding socio-economic status of the trial subjects. Obtaining vital information such as this would go along way in making the clinical trial process more transparent and hence reduce the negative connotations associated with them in the recent past.

Additionally regarding all clinical trials, the permission for which have been granted by the office of DCGI on or after 15th June 2009 have to be mandatorily registered on the clinical trial registry at www.ctri.in of Indian Council of Medical Research (ICMR). CDSCO has also issued guidelines for conducting inspection of clinical trial sites and sponsors or clinical research organizations (CROs).